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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,872	11/28/2006	Alison Helena Goodall	430160.401USPC	5465

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EXAMINER	
TSAY, MARSHA M	

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1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,872	GOODALL ET AL.	
	Examiner	Art Unit	
	Marsha Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *30-60* is/are pending in the application.

5a) Of the above claim(s) *49-60* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *30-48* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election of Group I, claims 30-48, to the species GPIIb, SEQ ID NO: 28, Pro, albumin microparticle, in the reply filed on November 11, 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-29 are canceled. Claims 49-60 have been withdrawn from further consideration by the examiner because they are draw to non-elected inventions. Claims 30-48, to the species GPIIb, SEQ ID NO: 28, Pro, albumin microparticle, are currently under consideration.

Priority: The request for priority to UK 0323378.0, filed October 7, 2003, is acknowledged. A certified copy of the foreign priority document has been filed in the instant case on April 6, 2006, and is in a non-English language.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims recite a fibrinogen-binding sequence of a platelet membrane glycoprotein comprising SEQ ID NO: 6 or a variant thereof. *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." As stated above, a fibrinogen-binding sequence of a platelet membrane glycoprotein comprising SEQ ID NO: 6 or a variant thereof. However, the skilled artisan cannot necessarily envision the detailed structures of ALL of the variants of a fibrinogen-binding sequence of a platelet membrane glycoprotein comprising SEQ ID NO: 6 that have the same functional activity as the wild-type SEQ ID NO: 6 because nowhere in the specification is it described which amino acids are even essential and critical for the wild-type sequence to maintain its functionality, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making

it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claims 30-32, 36-37, 38-39, 42-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims recite an insoluble carrier bound to a peptide. *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." As stated above, an insoluble carrier bound to a peptide. However, the skilled artisan cannot necessarily envision the detailed structures of ALL insoluble carriers bound to a peptide or all peptides that are bound to an insoluble carrier because while the specification provides some examples of insoluble carriers and peptides, it does not provide support for all insoluble carriers and all peptides. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making it. The compound itself is required. See *Fiers v. Revel*, 25

USPQ2d 1601 at 1606 CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites an agent which comprises an insoluble carrier bound to a peptide. Since it is unclear what the agent is, for examination purposes, an insoluble carrier that is bound to a peptide would reasonably be an agent. Further, regarding claim 30(i), 30(iii), the terms "is capable of" and "when" renders the claim indefinite because it is unclear whether the limitations following the terms are part of the claimed invention. See MPEP § 2173.05(d).

Claim 31 recites the terms "upon" and "preferentially", which renders the claim indefinite because it is unclear whether the limitations following the terms are part of the claimed invention.

Claims 32-33, 38 recite the peptide comprises a sequence obtained from a fibrinogen-binding region of a platelet membrane glycoprotein. It is unclear how the sequence is "obtained" from the fibrinogen-binding region. Further clarification is requested. It appears that the peptide is a fibrinogen-binding sequence of a platelet membrane glycoprotein.

Claim 48 recites the peptide is bound to the carrier by a covalent bond... For clarity, it is believed that the bond between said peptide and said carrier is a disulfide bond.

Claims 34-37, 39-47 are included in this rejection because they are dependent on the above claims and fail to cure its defects.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-35, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yen (US 6391343) in view of D'Souza et al. (1991 Nature 350: 66-68; IDS 11.28.06). For examination purposes, claim 30 is interpreted as: an injectable pharmaceutical product, comprising an insoluble carrier bound to a peptide, said peptide is not fibrinogen. Further, it should be noted that the use of open claim language "comprising" allows for additional components; therefore, the instant pharmaceutical product could reasonably include additional components, i.e. other proteins and peptides bound to the insoluble carrier, as long as one peptide that is bound to the insoluble carrier is not fibrinogen.

Yen discloses an albumin particle where fibrinogen is non-covalently attached to the particle (col. 44 lines 25-26). Yen further discloses that biologically active molecules can be incorporated within, on the surface, or near the surface of said albumin particle

(col. 25 lines 23-26). Yen discloses platelet membrane glycoprotein IIb peptide is an active molecule that can be incorporated with the albumin particle (col. 35 line 35). Yen does not explicitly teach a glycoprotein IIb peptide.

D'Souza et al. disclose that peptide B12 (TDVNGDGRHDL) (i.e. instant SEQ ID NO: 28) is a glycoprotein IIb peptide that inhibits platelet aggregation and binding of fibrinogen to platelets (p. 66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Yen by incorporating the B12 peptide of D'Souza et al. onto the albumin particle of Yen (claims 30-35, 42-44). Since Yen discloses that said albumin particle can be injected to help in clot formation, one of ordinary skill would be motivated to incorporate the B12 peptide of D'Souza et al. onto said albumin particle since the B12 peptide has been implicated to mediate platelet aggregation.

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

Regarding claims 45-46, Yen discloses that the size of the albumin particles can be 50 to about 5000 nm (col. 6 lines 10-11). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). MPEP 2144.05.

Regarding claim 47, Yen discloses that said biologically active molecules can be incorporated on the surface of or near the surface of said albumin particle and further discloses agents that can be covalently bonded to the albumin particle besides fibrinogen, therefore, it would be reasonable for one of ordinary skill to know that a covalently bonded biologically active molecule (i.e. B12 peptide) to said albumin particle would be within the scope of Yen.

Claims 36-41, 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yen (US 6391343) in view of D'Souza et al. (1991 Nature 350: 66-68; IDS 11.28.06) and Doolittle (1994 Haemostasis and Thromboses: 491-513; IDS 11.28.06). The teachings of Yen in view of D'Souza et al. are outlined above. Yen in view of D'Souza et al. do not teach an amino terminus sequence Gly-(Pro/His)-Arg-Xaa (instant SEQ ID NO: 36), where Xaa = Pro.

Doolittle discloses amino terminal sequences on fibrinopeptides are contact sites for polymerization (p. 500). Doolittle discloses Gly-Pro/His-Arg-Pro peptides bind to fibrinogen and affects clotting time (p. 500, also table 21.2, 21.3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Yen in view of D'Souza et al. by further incorporating the Gly-Pro/His-Arg-Pro peptides of Doolittle to the amino terminus of the B12 peptide of D'Souza et al. (claims 36-41, 48). The motivation to do so is given by Doolittle, which disclose that Gly-Pro/His-Arg-Pro peptides bind to fibrinogen and affects clotting time.

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-31, 36-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 11997540 ('540). Although the conflicting claims are not identical, they

are not patentably distinct from each other because both the instant claims and the '540 claims are drawn to a product comprising an insoluble carrier bound to a peptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marsha Tsay/
Patent Examiner, Art Unit 1656

January 14, 2012